



March 27, 2014

Exact Sciences Announces FDA Advisory Committee Unanimously Recommends Approval of Cologuard

First of its Kind Stool-based DNA Screening Test for Colorectal Cancer

MADISON, Wis.--(BUSINESS WIRE)-- [Exact Sciences Corp.](http://www.exactsciences.com) (Nasdaq: EXAS) today announced that the U.S. Food and Drug Administration's (FDA) Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee determined by a unanimous vote of 10 to zero that Exact Sciences has demonstrated safety, effectiveness and a favorable risk benefit profile of Cologuard®, the company's stool-based DNA (sDNA), non-invasive colorectal cancer screening test.

"We are pleased the Committee strongly supported Cologuard's approval," said Kevin T. Conroy, chairman and chief executive of Exact Sciences. "We look forward to continuing our work with the FDA to complete its review of Cologuard and remain committed to addressing the growing unmet needs in colorectal cancer screening. We thank the FDA and its advisory committee for its careful consideration of Cologuard. We also appreciate the opportunity to participate in the innovative FDA/CMS parallel review program. "

In the company's 10,000-patient, 90-site DeeP-C pivotal trial—one of the most extensive colorectal cancer screening studies ever conducted in the United States—Exact Sciences' Cologuard found 92.3% of colorectal cancer in average risk patients based on a combination of DNA and hemoglobin markers. Exact Sciences submitted the final module of its PMA for Cologuard on June 7, 2013, and the application includes data from that study, which was published online on March 19, 2014, in the *New England Journal of Medicine*. The peer-reviewed study, "[Multi-target Stool DNA Testing for Colorectal-Cancer Screening](#)" will also appear in the journal's April 3, 2014 print issue.

The FDA is not bound by the recommendation of its advisory committee, but will consider the committee's guidance as it evaluates the Cologuard PMA.

About Exact Sciences Corp.

Exact Sciences Corp. is a molecular diagnostics company focused on colorectal cancer. The company has exclusive intellectual property protecting its non-invasive, molecular screening technology for the detection of colorectal cancer. Stool-based DNA technology is included in the colorectal cancer screening guidelines of the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer. For more information, please visit the company's website at www.exactsciences.com.

Certain statements made in this news release contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. Forward-looking statements in this news release may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, anticipated results of our pivotal clinical trial, expectations concerning our ability to secure FDA approval of our Cologuard test, expected license fee revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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